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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,060	05/25/2001	James W. Whittaker	HME/8134.003	4178

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EXAMINER
PAK, YONG D

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/866,060	WHITTAKER ET AL.	
	Examiner	Art Unit	
	Yong Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-15 are pending.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-12) in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the protein of Group II is linked to Group I. This is not found persuasive because the method claims of Group I is drawn to producing a galactose oxidase and the protein of Group II is drawn to a fusion protein. More importantly, DNA and proteins are patentably distinct inventions. DNA and polypeptide are different compounds, each with its own chemical structure and function, and they have different utilities.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4, 8 and 11, the mere recitation of the name "gla" is insufficient to convey with clarity that which applicant sees as the invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, 6, 8 and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Golightly et al.

Golightly et al. (U.S. Patent 6,277,612) teach DNA encoding a galactose oxidase linked to an *Aspergillus niger gla* signal peptide and an inducible promoter that regulates transcription of the sequence encoding the construct (claims 13 and 16,

Columns 10-13 and Column 11). Golightly et al. also teach vectors comprising said DNA construct (claims 14-15 and 17-18 and Columns 13-17). Further, Golightly et al. also teach a method of producing the galactose oxidase using the vectors comprising the construct (claim 19 and Columns 10-17). Therefore, the teachings of Golightly et al. anticipate claims 1, 4, 6, 8 and 10-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 6-7, ~~9~~-10 and ~~12~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Golightly et al. in view of Zamost et al. Keep

Golightly et al. (U.S. Patent 6,277,612) teach DNA encoding a galactose oxidase linked to a signal peptide and an inducible promoter that regulates transcription of the sequence encoding the construct, vector comprising the DNA and a method of producing the protein, as discussed above.

The difference between the reference of Golightly et al. and the instant invention is that the reference of Golightly et al. does not teach a DNA encoding the galactose oxidase linked to methanol-inducible promoter or producing the protein in *Pichia spp*.

Zamost et al. a method for producing a target polypeptide in a Pichia host cell wherein the polypeptide is under the control of a methanol-inducible promoter and a vector comprising the target polypeptide and the methanol-inducible promoter (claims 1 and 11 and Columns 3-10). Zamost et al. teach that methylotrophic yeasts such as a *Pichia,* are attractive candidates for use in recombinant protein production systems (Column 1, lines 19-65).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a methanol-inducible promoter to produce the protein in a *Pichia* host. The motivation of using a methanol-inducible promoter and a Pichia host is to effectively produce recombinant proteins. One of ordinary skill in the art would have had a reasonable expectation of success since Pichia hosts are routinely used in the art for the production of recombinant proteins and since methanol-inducible promoters have been used successfully in inducing proteins.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golightly et al. in view of Montague-Smith et al.

Golightly et al. (U.S. Patent 6,277,612) teach a method of producing a galactose oxidase, as discussed above.

The difference between the reference of Golightly et al. and the instant invention is that the reference of Golightly et al. does not teach a method of producing the galactose oxidase by activating the enzyme with an oxidant.

Montague-Smith et al. Teach that galactose oxidases can be activated by treatment with one-electro oxidants, such as ferricyanides (page 354, 1st and 2nd paragraph). The need for this activation arises because galactose oxidases have a tendency to exist as a mixture of oxidized active and reduced inactive forms (page 353).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a methanol-inducible promoter to produce the protein in a *Pichia* host. The motivation of using a methanol-inducible promoter and a Pichia host is to effectively produce recombinant proteins. One of ordinary skill in the art would have had a reasonable expectation of success since Pichia hosts are routinely used in the art for the production of recombinant proteins and since methanol-inducible promoters have been used successfully in inducing proteins.

Claims 1, 4, 6, 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over McPherson et al. and Ward et al.

McPherson et al. teach DNA encoding a galactose oxidase, vector comprising said DNA and a method of producing the protein.

The difference between the reference of McPherson et al. and the instant invention is that the reference of McPherson et al. does not teach a DNA encoding the galactose oxidase linked to a signal peptide.

Ward et al. teach a fusion nucleic acid molecule encoding a construct comprising an *Aspergillus niger* glucoamylase (gla) and a target polypeptide (page 7), expression vectors containing the fusion nucleic acids, a transformed yeast and a process for expressing and secreting high levels of the target polypeptide (page 3). Ward et al. teach that the *A. niger* gla, a secretory sequence, can be used to express heterologous genes in yeast (page 2, 1st paragraph). Ward et al. teach that such expression system increases the secretion of the target polypeptide in yeast. Ward et al. also teach several promoters that regulate transcription of the sequence encoding the protein (page 16 through page 17).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a DNA encoding a fusion protein comprising of an *A. niger* gla and a target protein, a galactose oxidase, a vector comprising the construct and to produce the protein. The motivation of making such a construct is to increase secretion of the target protein in yeast, thus increasing the yield of the protein. One of ordinary skill in the art would have had a reasonable expectation of success since production and secretion of proteins linked to a A. niger gla signal sequence have been carried out successfully in the art and making a fusion protein

comprising a target protein and a signal peptide sequence is performed routinely in the art.

Claims 3, 5, 7, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over McPherson et al. in view of Ward et al. as applied to claims 1, 4, 6, 8 and 10-11 above, and further in view of Zamost et al.

McPherson et al. and Ward et al. in combination teach DNA encoding a galactose oxidase linked to a signal peptide and an inducible promoter that regulates transcription of the sequence encoding the construct, vector comprising the DNA and a method of producing the protein, as discussed above.

The difference between the two references and the instant invention is that the combined reference does not teach the fusion protein linked to a methanol-inducible promoter or producing the protein in *Pichia spp*.

Zamost et al. a method for producing a target polypeptide in a Pichia host cell wherein the polypeptide is under the control of a methanol-inducible promoter and a vector comprising the target polypeptide and the methanol-inducible promoter (claims 1 and 11 and Columns 3-10). Zamost et al. teach that methylotrophic yeasts such as a *Pichia,* are attractive candidates for use in recombinant protein production systems (Column 1, lines 19-65).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a methanol-inducible promoter to produce the protein in a *Pichia* host. The motivation of using a methanol-inducible

promoter and a Pichia host is to effectively produce recombinant proteins. One of ordinary skill in the art would have had a reasonable expectation of success since Pichia hosts are routinely used in the art for the production of recombinant proteins and since methanol-inducible promoters have been used successfully in inducing proteins.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over McPherson et al. in view of Ward et al. as applied to claim 1 above, and further in view of Montague-Smith et al.

McPherson et al. and Ward et al. in combination teach a method of producing a galactose oxidase, as discussed above.

The difference between the two references and the instant invention is that the combined reference does not teach a method of producing the galactose oxidase by activating the enzyme with an oxidant.

Montague-Smith et al. teach that galactose oxidases can be activated by treatment with one-electro oxidants, such as ferricyanides (page 354, 1st and 2nd paragraph). The need for this activation arises because galactose oxidases have a tendency to exist as a mixture of oxidized active and reduced inactive forms (page 353).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a methanol-inducible promoter to produce the protein in a *Pichia* host. The motivation of using a methanol-inducible promoter and a Pichia host is to effectively produce recombinant proteins. One of ordinary skill in the art would have had a reasonable expectation of success since

Pichia hosts are routinely used in the art for the production of recombinant proteins and since methanol-inducible promoters have been used successfully in inducing proteins.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

November 15, 2002

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